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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,465	12/09/2003	Jeffrey A. Whitsett	10872/0507287	5274

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EXAMINER	
MONTANARI, DAVID A	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
01/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/731,465	WHITSETT ET AL.	
	Examiner	**Art Unit**	
	David Montanari	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *39, 40 and 42*.
   Claim(s) withdrawn from consideration: *1-38, 41 and 43-75*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 11/21/2008

13. ☐ Other: _____.

/Peter Paras, Jr./
Supervisory Patent Examiner, Art Unit 1632

Continuation of 11. does NOT place the application in condition for allowance because: Applicants arguments and amendments to the claims are not persuasive.

Rejection under 35 U.S.C. 112, first paragraph

Claims 39, 40 and 42 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record in the office actions mailed on 4/11/2007, 7/14/2006, 11/5/2007 and 8/21/2008.

Applicants Arguments and the Declaration by Dr. Whitsett

It appears that Applicants arguments are exactly as those presented in paragraphs 6 and 7 of Dr. Whitsett's declaration, thus a combined response will be made below. Further, it appears that Applicant has inadvertently copied part of the examiner's last office action, particularly the enablement rejection (pg. 6 beginning with the last sentence bridge pg. 7) mailed on 8/21/2008 and somehow presented this copied region as arguments, in this regard, these arguments are not considered.

Applicants argue in amendment filed on 11/21/2008 that they have shown, in the declaration by Dr. Whitsett, that surfactant proteins (SP-D, SP-C, and SP-B) have been delivered intratracheally in mice; sheep and rabbits, mixed with carrier lipids to enhance spreading and delivery throughout the lung. Applicants continue that mixtures of SP-B and SP-C in lipid extracts of cow/pig lungs or surfactant isolated from lungs are routinely given for treatment of acute respiratory distress syndrome affecting pre-term infants and is a standard therapy (see Jobe, A.H. Pulmonary surfactant therapy. N. Engl. J. Med. 1993 328:861-868,1993).

Applicants continue that the delivery of the SP-C proteins to the lungs would be expected to act as a treatment of airway hyperresponsiveness and/or airflow limitation associated with respiratory disease involving an inflammatory response in a subject. Applicants argue that SP-C proteins delivered to the lung would be expected to act as a treatment since 1) the protein is a surface acting agent, 2) is in direct contact with the cells in the alveoli of the lung and 3) does not need to be effective at systemic delivery through the lung cells as with many other treatments. Applicants continue to argue that the present treatment with SP-C is a nonspecific treatment that will work regardless of the underlying source of inflammation and that a lack of SP-C results in inflammation in mice in the absence of infection. Applicants conclude that SP-C decreases inflammation after bacterial responses and also binds endotoxins and that SP-C decreases lung inflammation. While the declaration by Dr. Whitsett has been considered, these arguments are not persuasive.

Response to Arguments

While Applicant has argued that therapy using SP-C protein extracts has been used for the treatment of acute respiratory distress syndrome in pre-term infants, the claimed method still encompasses any SP-C therapeutic. While dependent claim 40 defines the therapeutic as a protein, claim 39 recites that "a formulation comprising a SP-C therapeutic" is delivered to a subject. While the elected invention is drawn to an SP-C therapeutic that is a protein, the claimed method still encompasses any SP-C therapeutic, which includes DNA, siRNA, mtDNA, RNAi, small molecules etc. which as the previous Final Rejection (pg. 5 parag. 2) mailed on 8/21/2008 taught was unpredictable.

Applicants arguments regarding the role of SP-C, its effect on inflammation and that SP-C protein administration will work regardless of the underlying source of inflammation are also not persuasive since again the term "associated" is problematic with respect to the claimed method because the skilled artisan cannot determine what is the cause of airway hyperresponsiveness and/or airflow limitation. Since the cause of airway hyperresponsiveness and/or airflow limitation could be inflammation or another cause such as emphezema the skilled artisan could not predictably treat a subject if the cause of the illness is not known (Final, 8/21/2008, pg. 7 lines 2-4). What is not clear to the skilled artisan is whether airway hyperresponsiveness and/or airflow limitation is related to the respiratory disease or the inflammatory response, since again its an association. If airway hyperresponsiveness and/or airflow limitation is the result of the respiratory disease and not just an inflammatory response then the skilled artisan could not reasonably expect that by delivering an SP-C protein that airway hyperresponsiveness and/or airflow limitation will be treated (Final, 8/21/2008, pg. 7 lines 9-12).

In summary, the claimed method remains broad with respect to the type of SP-C therapeutic administered to the subject and the skilled artisan would require an undue amount of experimentation without a predictable degree of success to practice the claimed method since underlying cause of hyperresponsiveness and/or airflow limitation would not be known.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID MONTANARI whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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